IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Xinqi Liu.		
		Group Art Unit:	1794
Serial No.:	10/523,622		
		Examiner:	Nikki H. Dees
Filed:	February 4, 2005		
		Confirmation:	2198

For: PROCESS FOR PRODUCING SOY PROTEIN

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Declaration under 37 C.F.R. §1.132 by Mr. Hiroyuki Kato in the above-identified application.

I, the undersigned, Hiroyuki Kato, declare and state that:

1. I am an employee of the Fuji Oil Co., Ltd., an assignee of the subject patent application having serial no. 10/523,622.

2. My education and professional experience as an expert in the area of Food Science are set forth on the attached copy of my Curriculum Vitae.

3. I have read and understand U.S. Patent Application Serial No. 10/523,622, entitled "PROCESS FOR PRODUCING SOY PROTEIN," and I submit this Declaration in its support.

4. I have read and understand the September 3, 2008 Non-Final Official Action issued in the above-identified case.

5. I have read and understand the publication of Muralidhara, et al. (U.S. Patent No. 6,630,195), General Foods (JP 44-6211 B), and Koski, et al. (U.S. Patent No. 3,653,912), cited by the Examiner.

6. In particular, I understand that in the September 3, 2008 Non-Final Official Action, the Examiner rejected claims 1, 4-11 and 13, alleging that it would have been obvious to modify the method for extracting oilseed material of Muralidhara with the step of acid washing as taught by General Foods before subjecting the soy protein to the counter-current extraction process. As a person skilled in the art, I respectfully disagree with this rejection.

7. Muralidhara describes a method for isolating a soy protein by two essential steps: i) an extraction step, for extracting protein from defatted soybean with an aqueous medium at a neutral to alkaline pH by counter-current extraction; and ii) an isolation step using membrane filtration, isolating soy protein on a membrane from a clarified extract obtained by the extraction step (col. 5, lns. 36-44 and FIG. 5). Muralidhara also discloses an alternative isolation method, which includes an additional step of spray drying the retentate collected on the filtration membranes to form a dry powdered product (col. 16, lines 3-12). However, it is duly noted that this step invariably occurs after the membrane filtration step.

8. General Foods describes a method for isolating soy protein by three essential steps: i) an acid-washing step, removing the whey and carbohydrates; ii) an extraction step, extracting protein from the acid-washed soybean slurry; iand iii) an isolation step using acid-precipitation, isolating the protein from the protein extract obtained by the extraction step (pg. 2, lns. 18-29).

9. Finally, Koski discloses a process for modifying soy protein where the protein is kept above the isoelectric point to keep the protein in solution. The soy protein is then used directly from solution, or may be spray-dried.

10. None of the cited references, *i.e.*, Muralidhara, General Foods, and Koski, alone or in combination describe, teach or suggest the method for isolating soy-protein in high purity and yield by three essential steps: i) an acid-washing step, removing the whey and carbohydrates; ii) an extraction step by a counter-current extraction method; extracting protein from the acid-washed soybean slurry; and iii) sterilization and drying step; with an essential limitation that no acid precipitation occur after the extraction. The isolated soy-protein product of a high quality, obtained by the claimed method of the instant application, is already been commercialized under the product name "PROLINA 900" as protein powder (see Exhibit A), and under the product name "NEW FUJIPRO 3000" as meat packing food powder (see Exhibit B).

11. The instant invention requires for the soy-protein production process to occur under the recited steps listed in Table 1(A) in order to produce soy-protein of high purity and yield. The below mentioned comparative study readily demonstrates the significance of performing the soy-protein isolation with an acid wash but without an acid precipitation step. On

the other hand, Muralidhara is **silent about** an acid wash or an acid precipitation step, whereas General Foods employs both, acid wash **and** acid precipitation step together.

12. I conducted a comparative study to demonstrate the significance of performing soy-protein isolation without an acid precipitation step after the extraction step on the flavor, color, and purity of the soy-protein product. In summary, the soy-protein was prepared and isolated using the steps as outlined in Table 1. Specifically, soy-protein (A) was isolated according to the steps as disclosed in Examples 1-2 and 2 of the instant specification (claimed process). Soy-protein (C) was isolated according to the steps as disclosed in the comparative Example 1 of the instant specification (a conventional method of soy-protein isolation), and soy-protein (B) was obtained by further subjecting the soy-

Table 1 Steps in soy-protein isolation

(A) **(Examples 1-2 and 2)**	**(B)** **(A) + Acid precipitation**	**(C)** **(Comparative Example 1)**
Defatted soybean powder	Defatted soybean powder	Defatted soybean powder
↓	↓	↓
Acid washing	Acid washing	Protein extraction
↓ → whey	↓ → whey	↓ → Extraction residue
Acid-washed slurry	Acid-washed slurry	Defatted soymilk
↓	↓	↓
Counter-current protein extraction	Counter-current protein extraction	**Acid precipitation**
↓ → Extraction residue	↓ → Extraction residue	↓ → whey
Soy-protein extract solution	Soy-protein extract solution	Neutralization
↓	↓	↓
Sterilization	**Acid precipitation**	Sterilization
↓	↓ → whey	↓
Drying	Neutralization	Drying
↓	↓	↓
Soy-protein	Sterilization	Soy-protein
	↓	
	Drying	
	↓	
	Soy-protein	

protein (A) to an acid precipitation step under the same conditions as presented in Comparative Example 1 (soy-protein (C)) after the extraction step but before the neutralization, sterilization and drying steps. Protein yield (%) was determined by calculating the weight ratio of the obtained soy-protein products relative to the weight of the material used (defatted soybean powder). Protein content (solids) was determined by first obtaining nitrogen content by the Kjeldahl method and subsequently the obtained nitrogen content was multiplied by the coefficient 6.25 to give a crude protein content, which was shown by moisture basis. The protein content, ash content, and flavor of the isolated soy-protein product was measured and summarized in table 2.

13. As shown in Table 2, comparison of isolated soy-proteins (A) – (C) for their protein contents, ash contents and flavor demonstrated that (B) is inferior to (A) in flavor. Also, while (C) showed the same protein content as (A), *i.e.*, 91%, its flavor like (B) was also significantly inferior to (A). Thus, the comparative study readily demonstrates the criticality of the protein isolation steps as stipulated in the presently pending claims, *i.e.*, acid wash step but no acid precipitation step, and that the isolated soy-protein obtained by the method of the present invention has as high protein content as that of the conventional products yet maintaining superior quality such as flavor. Such quality superiority is thought to be based on conducting the claimed protein isolation without a conventionally conducted acid precipitation step.

Table 2: Results in the comparative study

	Soy protein		
	(A)	(B)	(C)
Protein content (dry basis)	91%	91%	91%
Ash content (dry basis)	5%	5%	5%
Flavor	Refreshing taste without sense of soybean smell, astringency, etc.	Sense of astringency, and irritating sense on the tongue	Sense of bean smelling and astringency

14. I also conducted a comparative study to examine the production characteristics of soy-protein of the instant invention and compared them to the production characteristics of soy protein of the General Foods approach. In summary, the soy-protein was prepared and isolated using 1) the steps as outlined in Examples 1-2 and 2 of the instant specification (claimed process; IAP[1] 1 & 2) and 2) the steps as outlined in Examples 1 and 2 of General Foods application, however, without an acid precipitation step (GFP[2] 1 & 2). The comparison was conducted to analyze the yields and protein content of the soy-product attained by the claimed method versus the soy-product attained by the General Foods method even without the acid precipitation step. The yields and protein contents of each set is shown in Table 3. In order to establish proper comparison for the protein content, the yield of GFP-1 (41%) was made to be the same as that of the IAP-1 (41%) by adjusting the amount of the extract solution. Alternatively, to establish proper comparison for the yield, the protein content (87%) of GFP 2 was made to be the same as that of the IAP-1 by adjusting the amount of the extract solution.

Table 3: Production characteristics of soy-protein

		Method of General Foods				Method of the present invention			
		GFP 1		GFP 2		IAP 1		IAP 2	
Before Extract-ion (Acid washing) pH	Soluble (Extract-ion) pH	Yield (%)	Protein content (solids)	Yield (%)	Protein content (solids)	Yield (%)	Protein content (solids)	Yield (%)	Protein content (solids)
4.2	7.0	41%	80%	20%	87%	41%	87%	39%	91%

[1] IAP – Instant Application Product – an isolated soy-protein produced by the claimed method
[2] GFP – General Foods Product – an isolated soy-protein produced by the method outlined in Examples 1 and 2 of the General Foods Application (JP 44-6211 B).

15. Comparison of the sample obtained by the production method of the present application and the sample obtained by the General Foods production method revealed that while the protein yield were adjusted to be the same (41%), the protein content of IAP-1 (87%) was higher than the protein content of GFP-1 (80%) by 7%. This demonstrates that the soy-product attained by the claimed process produces the protein of higher purity level if the acid precipitation step is not employed by the General Foods method. Therefore, the protein purity had to be improved by adding the acid precipitation step. However, addition of the acid precipitation step leads to quality deterioration as shown in the aforementioned comperative study (see section 13 above). Furthermore, when the yield was increased by the method of General Foods, flavor deterioration was caused in addition to the decrease in protein content due to contamination of components other than protein.

16. Comparison of the sample obtained by the production method of the present application and the sample obtained by the General Foods production method revealed that while the protein content were adjusted to be the same (87%), the protein yield of IAP-1 (41%) was significantly higher than the protein yield of GFP-2 (20%) by 21%. This demonstrates that in the method of General Foods, the yield was dramatically decreased when the protein content was increased to the protein purity level of the isolated soy-protein attained by the claimed method.

17. On the other hand, comparison of the sample IAP-2 obtained by the method of the present application and the sample GFP-1 obtained by the method of General Foods demonstrated that the protein yield of IAP-2 was decreased only slightly by about 2% compared to that of GFP 1, but the protein content of IAP-2 was increased by as much as 11% compared to GFP-1. Thus, it has been shown that the isolated soy-protein of high purity can be obtained.

18. While it is possible to increase the yield to 87% by increasing the soluble pH, however, such pH might cause undesirable flavor deterioration and lysinoalanine generation.

19. Thus, it is my experience and my opinion, as one skilled in the art of Food Science, that the soy-protein isolation process disclosed in the present application and the soy-protein isolation process disclosed in the combination of Muralidhara, General Foods, and Koski are not the same, nor are they similar. The processes disclosed in the instant specification provides superior product quality by combining the acid washing step and the counter-current protein extraction step, which results in a high yield as well as being economical. On the other hand, the process disclosed in Muralidhara, General Foods, and Koski are designed to treat defatted soybean powder by either alkaline extraction and membrane filtration (Muralidhara) or acid washing , extraction, and acid precipitation steps (General Foods). However, such steps difiltration. For instance, the method proposed by General Foods will produce a soy-protein product with inferior flavor and color, whereas without the acid precipitation step, it will produce a soy-protein product of inferior yield and protein content (see comparative studies discussed above).

20. Therefore, a scientist in the field of Food Science would not be able to use the processes disclosed in Muralidhara, General Foods, and Koski along or in combination in order to obtain the soy-protein product of superior quality with high yield and protein content comparable to the presently claimed method disclosed in the instant specification.

21. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so

made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Respectfully submitted,

Date : January 30, 2009

Hiroyuki Kato

Mr. Hiroyuki Kato

EXHIBIT A
Brochure of PROLINA 900" (SOYAFARM)

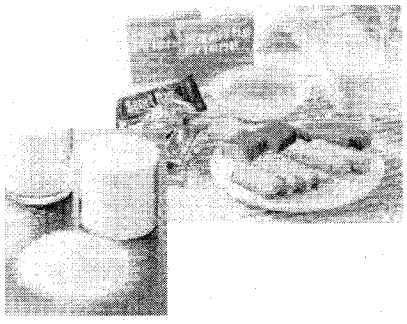
良質な大豆たん白素材で品質アップ！

粉末状分離大豆たん白
プロリーナ900のご紹介

「プロリーナ900」は、従来製法を抜本的に見直し、より風味にこだわった新規製法（特許出願済）により開発された粉末状分離大豆たん白です。従来品よりも大幅に風味を向上しています。優れた風味と栄養価の特長を生かして健康食品などの分野で一層の幅広い製品開発のお役立てに繋がるものと思っております。

【標準分析値】

水分		5.8%
たん白質（無水換算）		90.5%
脂質		0.5%
炭水化物		4.4%
灰分		4.0%
ミネラル	ナトリウム	1.30%
	カリウム	0.17%
	カルシウム	0.21%
	マグネシウム	90.5mg/100g
	亜鉛	2.7mg/100g
	銅	1.4mg/100g
	鉄	7.9mg/100g
エネルギー		363kcal



【主な特性・使用方法】
1. 大豆臭が無く、すっきりとした良好な風味が特徴です。従来以上の高配合化が可能です。
2. 従来品では難しかった柑橘系風味との相性が良好です。
3. ホットドリンクに配合しても従来品より匂い立ちが少ないことが特徴です。
4. 粉体を直接水に添加してもダマになり難く、分散性が良好です。
5. 低粘度で粉っぽさの無い、飲み口の良い水溶液が調製でき、粉末飲料等の飲料に好適です。
6. 特定保健用食品（血中ｺﾚｽﾃﾛｰﾙ低下）の素材としてもご利用いただけます。

【主な用途】
・プロテインパウダー、粉末スープ、粉末飲料などの健康食品
・製菓、製パン、焼き菓子、加糖ミックス粉 等

【原材料表示】
脱脂大豆、 乳化剤

【包装形態】
紙袋 10kg

【細菌分析値】

一般菌	3000/g以下
耐熱菌	100/g以下
大腸菌群	陰性

【ｱﾚﾙｷﾞｰ情報】 【大豆原産国】
大豆 米国

【ｱﾐﾉ酸組成】 (FAO/WHO/UNU1985提唱)
2歳以上の全ての年齢層でｱﾐﾉ酸ｽｺｱが100

	たん白質100g中(g)		たん白質100g中(g)
ｱﾗﾆﾝ	4.1	ﾘｼﾞﾝ	6.1
ｱﾙｷﾞﾆﾝ	7.6	ﾒﾁｵﾆﾝ	1.3
ｱｽﾊﾟﾗｷﾞﾝ酸	11.6	ﾌｪﾆﾙｱﾗﾆﾝ	5.3
ｼｽﾁﾝ	1.3	ﾌﾟﾛﾘﾝ	5.4
ｸﾞﾙﾀﾐﾝ酸	19.6	ｾﾘﾝ	5.1
ｸﾞﾘｼﾝ	4.1	ｽﾚｵﾆﾝ	3.8
ﾋｽﾁｼﾞﾝ	2.7	ﾄﾘﾌﾟﾄﾌｧﾝ	1.4
ｲｿﾛｲｼﾝ	4.5	ﾁﾛｼﾝ	3.7
ﾛｲｼﾝ	7.7	ﾊﾞﾘﾝ	4.6

【保存方法】
高温多湿や直射日光を避けて下さい

【賞味期限】
製造後180日

製造元
不二製油株式会社
蛋白加工食品カンパニー
蛋白素材部門
TEL(072)463-1057

販売元
フジプロテイン テクノロジー株式会社
本 社／TEL(03)5418-1865
大阪販売部／TEL(06)6213-7686

2008.5.30 改訂

EXHIBIT B
Brochure of "NEW FUJIPRO 3000" (SOYAFARM)

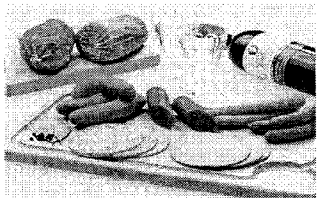
粉末状分離大豆たん白

ニューフジプロ3000のご紹介

「ニューフジプロ3000」は、食肉加工食品、調理加工食品用として開発された分離大豆たん白です。従来製法を見直した新規な大豆たん白抽出技術をﾍﾞｰｽに製品開発した従来品以上に風味、溶解性、色調に優れた分離大豆たん白です。
漬込み用として必要な機能を備えており、製品の品質、コスト、作業性等の点で皆様のお役に立つものと確信しております。

【標準分析値】

水分	5.8%
たん白質(無水換算)	88.5%
脂質	1.5%
灰分	5.1%
炭水化物	4.2%
エネルギー	364kcal



【主な特性・使用方法】

1. 大豆臭を除去しておりますので、非常に良好な風味です。
2. 溶液にした際の粘度が低く、肉中での分散性に優れ、調理加工後の製品の成形性が向上します。
2. 風味良好で低粘度のため、大豆たん白の高配合が可能です。
4. 泡立ちが少なく、水への分散性に優れており、作業性が良好です。

●ホモミキサー等を用いて、先ず大豆たん白を水に添加し、塊が残らないよう分散させます。その後、糖質、調味料、塩漬剤等を加え、肉類の漬込み液を調製します。

【主な用途】
食肉加工品 ： ロースハム ボンレスハム ベーコン
調理加工品 ： 焼豚 から揚げ とんかつ

【原材料表示】
脱脂大豆、食用植物油脂
乳化剤、酸化防止剤(亜硫酸塩)

【ｱﾚﾙｷﾞｰ情報】
大豆

【大豆原産国】
米国

【包装形態】
紙袋 10kg

【保存方法】
高温多湿や直射日光を避けて下さい

【賞味期限】
製造後180日

製造元
不二製油株式会社
蛋白加工食品カンパニー
蛋白素材部門
TEL(072)463-1057

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2008.5.30改訂

CURRICULUM VITAE

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NATIONALITY : JAPAN

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EDUCATION:

1994 - 1998 Department of Food Engineering, Faculty of Agriculture, Kyoto University

1998 - 2000 Department of Applied Life Sciences, Graduate School of Agriculture, Kyoto University

WORKING EXPERIENCE:

2000 - 2009 Fuji oil co., Ltd.

April 2000 - March 2008 Protein Development Department, Protein Division

April 2008 - 2009 Protein Development Department, Protein & Food Ingredients Division, Soy Protein, Processed Foods Company

Title: Assistant Manager